EXHIBIT 3

WALSH PIZZI O'REILLY FALANGA

ONE RIVERFRONT PLAZA
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

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VIA ECF AND FIRST-CLASS MAIL
Honorable Michael A. Hammer, U.S.M.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: ***Celgene Corporation v. Hetero Labs Limited, et al.***
Civil Action No. 2-17-cv-03387 (ES)(MAH) (D.N.J.) (CONSOLIDATED)

Dear Judge Hammer:

This firm, together with Kirkland & Ellis LLP, represents Defendant Teva Pharmaceuticals USA, Inc. ("Teva") in connection with the above-referenced matter. We write jointly on behalf of all Parties concerning Your Honor's instructions during the in-person conference held March 29, 2019 (ECF Nos. 316 & 324) that the Parties provide the Court with a joint letter outlining each party's position with respect to the remaining disputes in connection with Defendants' pending application to compel Celgene to produce documents in response to Defendants' first and second sets of requests for the production of documents and things (ECF Nos. 255, 268, 276), on which the parties have reached an impasse requiring resolution by the Court.

A. General Positions

1. Defendants' Position

Despite extensive meet and confer efforts, the Parties remain at an impasse with respect to four categories of documents presented in the Parties' prior letter briefing before the Court: Sections B (EntreMed Actions), C (lenalidomide/thalidomide actions), D (lenalidomide/thalidomide development), and H (Pediatric Exclusivity) of the Parties' letter briefing. *See* ECF No. 255; ECF No. 268; ECF No. 276.

Following 11 months of meeting and conferring, on November 29, 2018, Defendants moved to compel Celgene to respond to 22 requests for production of documents, grouped for convenience into nine categories of documents. *See* ECF No. 255 at 2. Although certain of these disputes have been since resolved, this resolution is attributable to compromises offered solely ***by Defendants***. Celgene did not begin proposing compromises until February 28, 2019—more than 13 months after the requests were served and after Defendants had already significantly narrowed the requests. Moreover, Celgene's proposed compromises—including the ones set forth by Celgene in the following section—have been wholly inadequate, as Defendants explain

below. Defendants' requests seek documents directly relevant to Defendants' invalidity contentions and asserted prior art, whereas the bulk of Celgene's production to date—consisting of portions of its New Drug Application ("NDA")—are traditionally relied upon by brand companies at trial as alleged evidence of invention and secondary considerations of non-obviousness. Throughout the conferral process, Celgene's relevance objections have been predicated on its disagreement with Defendants' contentions. This is not the proper standard for determining relevance. *See* Fed. R. Civ. P. 26.

To date, Celgene's allegedly voluminous production of "[redacted] while most defendants have produced thousands more documents. [redacted], but Celgene's patents, including the conception, diligence, and reduction to practice of the alleged invention, are also at issue. Celgene has through its own admission spent "years of research and development" on its products (ECF No. 251 (Celgene's Opening *Markman* Br.) at 2), [redacted] Defendants are entitled to adequate discovery to assess that purported research and development which Defendants' invalidity contentions put squarely at issue in this case.

2. Celgene's Position

Over the last year and a half, Celgene has responded to more than 100 Requests for Production from Defendants and produced [redacted]. While Defendants claimed at the March 29, 2019 in-person meet-and-confer that Celgene's production so far has been "self-serving" (Tr. at 7:3-9), this is not true. The parties have already resolved numerous disputes, and Celgene—while not conceding relevance—has agreed to produce documents (including the NDA) in response to the vast majority of Defendants' requests to avoid burdening the Court with disputes and to expedite this litigation. For example, Defendants' original motion to compel (D.I. 255) addressed nine categories of documents (designated as "A" through "I"). Celgene was able to resolve the majority of categories in Defendants' motion to compel through additional compromises and by agreeing to produce additional documents, leaving only categories B, C, D, and H in dispute. [redacted] This is so even though Defendants' products and ANDA, not Celgene's products and NDA, are at issue in this case.

In short, Defendants' characterization of Celgene's document production is incorrect. The research and development for the inventions at issue in this case—specific methods of using the drug pomalidomide for treating multiple myeloma [redacted] Notably, Defendants ***agreed to*** Celgene's proposed compromise production—a compromise Celgene made well before February of this year.

To be clear, documents concerning ***pomalidomide*** are ***not in dispute*** in this letter. Instead, the four remaining ***disputes*** concern ***other products.*** Defendants cannot establish relevance and proportionality for the documents they seek. Indeed, Defendants' requests are broad enough to cover the vast majority of documents within Celgene and cover products and patents that are irrelevant to this action. Nevertheless, Celgene offered reasonable compromise positions—both in numerous discussions prior to the in-person meet-and-confer and at the March 29 conference—to fully resolve each of these disputes. Defendants, however, now improperly use Celgene's proposed compromises as new baseline positions, and ask the Court to reward

Defendants with more. As explained below, Defendants' requests are overly broad, seek irrelevant documents, and will only create further disputes. Celgene, therefore, respectfully requests that the Court deny Defendants' four remaining requests as irrelevant, overly broad, unduly burdensome, and disproportionate to the needs of this case.

In the alternative, in an effort to fully resolve these disputes, and while not conceding relevance, Celgene would be willing to offer, or already has offered, the following compromises:

- For the "Section B (EntreMed Actions)" documents, Celgene would agree to produce, to the extent they exist and can be located after a reasonable search, [redacted]

- For the "Section C (Lenalidomide/Thalidomide Actions)" documents, Celgene has offered, and remains willing, to produce from the actions specifically identified in D.I. 276, to the extent they exist and can be located after a reasonable search: (1) invalidity/validity contentions and portions of expert reports concerning inventorship and secondary considerations regarding multiple myeloma; and (2) the unredacted transcripts for the depositions of Dr. Zeldis;

- For the "Section D (Lenalidomide/Thalidomide Development)" documents, Celgene has offered to produce: (1) a 30(b)(6) witness to testify regarding "[t]he [lenalidomide] protocols and trials described in the Declaration By Jerome B. Zeldis signed October 26, 2005 submitted during the prosecution of the application that issued as U.S. Patent No. 7,968,569, including the protocols and trials described in paragraphs 5-6 and Exhibits D-K" and "[t]he [lenalidomide] protocols and trials described in the Declaration By Jerome B. Zeldis signed May 30, 2006 submitted during the prosecution of the application that issued as U.S. Patent No. 7,968,569, including the protocols and trials described in paragraphs 5-6 and Exhibits D-G"; and (2) documents concerning the secondary considerations that Celgene has asserted in this case (including unexpected results), whether those materials support or refute Celgene's arguments. Celgene understands that this moots Defendants' request as it will provide sufficient information regarding the materials that Defendants seek; and

- For the "Section H (Pediatric Exclusivity)" documents, Celgene has agreed to produce materials concerning pediatric studies regarding pomalidomide and multiple myeloma, to the extent Celgene ever generates such materials.

B. Section B (EntreMed Actions)

1. Defendants' Position

Defendants request the production of settlement agreements and associated data and records, including any licenses or assignments, relating to the settlement of any of the EntreMed Actions.[1] Defendants' requests expressly include the asset purchase agreement between

[1] *Celgene Corporation v. Rogan et al.*, Civil Action No. 1:02-cv-02277-RBW (RBW) (D.D.C.); *EntreMed, Inc. v. Celgene Corporation.*, Civil Action No. 8:02-cv-03787 (DKC) (D. Md.); and

EntreMed, Inc. ("EntreMed") and Celgene as well as the "clinical data and records" that Celgene obtained from EntreMed. ECF No. 255 at 4; *id.*, Ex. 5 (DEFS_POM_00002015) at 2061–62.

Throughout the Parties' 14 months of conferring on this request, Celgene refused to produce any of the requested documents. During the Parties' March 29, 2019 in-court meet and confer, Celgene offered for the first time to produce a subset of the requested documents, limited to [redacted] to the extent they exist, and no settlement agreements. Then, on April 19, 2019 after reviewing Defendants draft of this letter, Celgene offered to produce [redacted]. This proffered scope of documents remains too narrow. As explained below, documents concerning pomalidomide, lenalidomide, and thalidomide, generally, are directly relevant to claims in this case and should be produced without further delay. Defendants' requests are both relevant and proportional to the needs of this case. *See* Fed. R. Civ. P. 26(b) & 34. *See also Zampetis v. City of Atlantic City*, No. 1:15-cv-01231-NLH-AMD, 2018 WL 5729905, at *2 (D.N.J. Nov. 2, 2018) ("Rule 26 is to be construed liberally in favor of disclosure, as relevance is a broader inquiry at the discovery stage than at the trial stage." (citation omitted)).

Improper Inventorship and Obviousness: As detailed in their invalidity contentions, Defendant assert improper inventorship with respect to Celgene's three patents in suit, U.S. Patent Nos. 8,198,262, 8,673,939, 8,735,428 ("MOT Patents"). Defendants claim that it was Dr. Robert D'Amato—inventor on U.S. Patent No. 5,712,291 ("the '291 patent")—(perhaps with others) that invented the subject matter of the patents-in-suit and that the work of EntreMed and Dr. D'Amato is invalidating prior art.[2] Moreover, Defendants continue to develop these theories through subpoenas seeking discovery from Dr. D'Amato and fromEntreMed, including requests for communications with Celgene before the MOT patents were filed and regarding this subject matter.

EntreMed is a former competitor of Celgene and was the exclusive licensee to patents filed in the 1990s covering the use of thalidomide and its analogs as anti-angiogenic agents for the treatment of blood born cancers, such as multiple myeloma. These patents list Dr. D'Amato as the sole inventor, and thalidomide analogs covered by these patents include pomalidomide and lenalidomide. One of these patents, the '291 patent, claims "3-aminothalidomide" and is listed as prior art in Defendants' invalidity contentions. Ex. 26 (12/15/2017 Rule 3.3 Contentions (MOT Patents and the '427 patent)) at 56–57. Celgene itself admits that 3-aminothalidomide is another name for pomalidomide. *See, e.g.*, ECF No. 1, Ex. C ('428 Patent) at claim 1; ECF No. 251 (Celgene's Opening *Markman* Br.) at 4 (identifying the chemical structure in claim 1 of the

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Children's Medical Center Corporation v. Celgene Corporation, Civil Action No. 1:13-cv-11573 (MLW) (D. Mass.).

[2] *See* Ex. 26 (12/15/2017 Rule 3.3 Contentions (MOT Patents and the '427 patent)) at 36–39, 56–57 (asserting '291 patent and D'Amato publications as prior art), 82, 103 (asserting EntreMed publications as prior art); ECF No. 255, Ex. 13 (12/15/2017 Rule 3.3 Contentions (MOT Patents and the '427 patent)) at 179–80 (asserting under § 102(f) and § 102(g)(2) that Dr. Zeldis did not invent the claimed subject matter and citing documents from the EntreMed Actions); Ex. 27 (1/25/2019 Rule 3.3 Contentions (U.S. Patent No. 9,993,467 (the "'467 patent"))) at 59 (asserting EntreMed pomalidomide formulations as prior art). Thus, Celgene's statement below that Defendants "do not have any inventorship claims in this case" is plainly false. *See also* ECF No. 276 at 3. Nor have Defendants ever stated they do not have any inventorship claims in this case.

'428 patent as pomalidomide); Ex. 28 (DEFS_POM_00002413) at 3611–13, ¶¶ 5–13 (complaint for *Celgene Corp. v. Rogan*, No. 1:02-cv-2277 (D.D.C. Nov. 19, 2002)) (in Federal pleadings, Celgene refers to the same chemical structure in claim 1 of the '428 patent as "3-amino thalidomide"));[3] Ex. 29 (Continuity Data for '291 Patent) at 2 (identifying U.S. Application No. 09/899,344 (the "'344 application") as a child); *see also* ECF No. 276, Ex. 21 at Fig. 1 (identifying "3-amino thalidomide" with the chemical structure for pomalidomide).[4]

After the filing of the '291 patent, Celgene filed its own patents on similar treatments, including U.S. Patent No. 6,316,471 ("the '471 patent). The '471 patent was listed before its expiration in the Orange Book for Pomalyst® and is identified as prior art in Defendants' invalidity contentions. ECF No. 255, Ex. 13 at 20–21. Celgene then sued the Patent Office and EntreMed when continuation patents to the '291 patent—the '344 application and U.S. Application No. 10/020,391 (the "'391 application"))—including claims to methods of treating undesired angiogenesis with pomalidomide, were allowed by the Patent Office. Ex. 28 (DEFS_POM_00002413) at 3610–24, ¶¶ 10-11, 33, 35-36, 49 (*Celgene v. Rogan* complaint).[5]

In that complaint, Celgene alleged, among other things, that "[t]he 'inventions' claimed in the '344 application, as amended, include methods that are the same invention as methods that are disclosed and claimed in the '471 patent" and that ["t]he compound referred to in the '344 application claims, as amended, as '3-amino thalidomide' and depicted by the structural formula [of pomalidomide] is exactly the same compound as the '471 patent discloses and claims." *Id.* at DEFS_POM_00003613, ¶¶ 12-13. *See also id.* at DEFS_POM_00003616, ¶ 29 ("Issuance of a patent on the '344 application in its current form would effectively nullify plaintiff's legal and economic rights under the '471 patent and give over to EntreMed the benefits of plaintiff's patented inventions."). EntreMed then filed a counter-suit against Celgene over inventorship rights to the '471 patent and "the method of using 3-amino thalidomide to treat diseases mediated by angiogenesis, such as cancer." Ex. 32 (DEFS_POM_00002413) at 3646–47 (complaint for *EntreMed, Inc. v. Celgene Corporation.*, No. 8:02-cv-03787 (D. Md. Nov. 21, 2002)); ECF No. 255, Ex. 10 (DEFS_POM_00003855–56 (EntreMed press release discussing lawsuits relating to the '291 patent to Dr. D'Amato)). Thus, at issue in the Celgene/EntreMed litigations was

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[3] Celgene's assertion that "the compound identified as '3-aminothalidomide' in the '291 patent is ***not*** pomalidomide" is undercut by its own pleadings in the *Celgene v. Rogan* action referring to the chemical structure of pomalidomide as "3-amino thalidomide."

[4] Although the Parties' dispute over the '291 patent's disclosure is more properly a subject for expert discovery, Defendants' invalidity contentions do contend that the '291 patent discloses pomalidomide. Ex. 26 (12/15/2017 Rule 3.3 Contentions (MOT Patents and the '427 patent)) at 56–57. The Patent Office agreed. Ex. 30 (DEFS_POM_00000130) (certificate of correction of the '291 patent) at 147–48; Ex. 31 (DEFS_POM_00002413 (allowing '344 application's claims to pomalidomide)) at 3355-56.

[5] Celgene's allegation that Defendants present "new arguments" is baffling, considering the *Celgene v. Rogan* action is identified in Defendants' Letter Application (ECF No. 255 at 4 n.2) and the complaint as well as the entire prosecution history of the '344 application are cited in Defendants' invalidity contentions as supporting claims under Sections 102(f) and 102(g)(2). *Id.*, Ex. 13 (12/15/2017 Rule 3.3 Contentions (MOT Patents and the '427 patent)) at 179–80 (citing Dkt. 19 from *Celgene v. Rogan*). Defendants also discussed these documents with Celgene at the in-court meet and confer.

inventorship over a patent Celgene has claimed covers Pomalyst® (i.e., the '471 patent) as well as methods that include treatment of cancers such as multiple myeloma with pomalidomide.

As reported in Celgene's 2002 Annual Report, the Celgene/EntreMed litigations ended with an "Asset Purchase Agreement" and the transfer to Celgene of EntreMed's exclusive license to the "thalidomide analog patents" and "associated clinical data and records." ECF No. 255, Ex. 5 (DEFS_POM_00002015) at 2061–62; Ex. 33 (DEFS_POM_00003842–44). Defendants' requests seek discovery of the agreements and the data package transferred as part of the settlement.[6]

Celgene argues that the requested documents cannot be relevant because they are "internal" or "confidential" documents now owned by Celgene and therefore not prior art. This is incorrect. Claims under 35 U.S.C. § 102(g)(2) do not require information to be public in order to be invalidating prior art. Section 102(g)(2) states that a person is entitled to a patent unless, "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (pre-AIA). The Federal Circuit has held that "secret" section 102(g) prior art can be invalidating prior art under 35 U.S.C. § 103 (obviousness) even if not known to the named inventor or the public.[7] *See, e.g.*, *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 976–77 (Fed. Cir. 2014) (finding competitor's prototype, which was not known to the public or named inventor prior to the invention priority date, was nevertheless invalidating prior art for both anticipation and obviousness). Celgene below relies on *Avanir Pharm., Inc. v. Actavis S. Atlantic LLC, et al.*, No. 11-704, D.I. 462 (D. Del. Dec. 20, 2013). But the court there was deciding a motion *in limine* to exclude testimony on records never produced in the litigation and that the parties ***agreed*** were not prior art. *Id.* at 52:14–18; 53:14–21. Here, by contrast, Defendants contend the requested information is Section 102(g)(2) prior art. *See Tyco Healthcare Grp.*, 774 F.3d 976–77; *Alexsam, Inc. v. Gap, Inc.*, 621 Fed. Appx. 983, 991 (Fed. Cir. 2015). As the remaining cases Celgene cites, which pre-date the Federal Circuit's *Tyco* decision, make clear, the burden of producing evidence of suppression or concealment is the patentee's (*i.e.*, Celgene's), and Celgene has made no such allegation to date. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1037 (Fed. Cir. 2001) and *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed. Cir. 2012). In any event, whether "internal" or not, there is nothing to support Celgene's claim that the data and records sought were "confidential" or concerned only "confidential" subject matter when kept by EntreMed, before they were obtained by Celgene.[8]

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[6] The EntreMed Actions also include the subsequent lawsuit against Celgene to enforce this settlement, and Defendants' requests also seek the settlement agreement terminating that dispute.

[7] The prior art status of the requested documents is not obviated by Celgene's subsequent claim of ownership because at the time of creation the documents were not owned by Celgene. *See* 35 U.S.C. § 103(c) (pre-AIA); *Indus. Tech. Research Inst. v. Pacific Biosciences of Cal.*, 640 F. App'x 871, 883 (Fed. Cir. 2016) (holding that the common ownership requirement of Section 103(c) is "at the time of the invention was made").

[8] The Discovery Confidentiality Order entered in this case is sufficient protection for any nonparty confidential information produced in this case. Defendants are in the process of conferring with third-parties CASI Pharmaceuticals (EntreMed's successor) and Dr. D'Amato regarding subpoenas for documents and deposition testimony served on them in this litigation. During this conferral process, neither third party has claimed that the protections of the

Proportionality: Celgene's narrowing of this request to [redacted] ignores a substantial set of relevant documents. Throughout the meet and confer process, Celgene has insisted that relevance be limited to pomalidomide [redacted], the prior art cited in Defendants' invalidity contentions is not so limited. Cancers such as multiple myeloma are associated with undesired blood vessel formation (or "angiogenesis"). This awareness led Dr. D'Amato and others to investigate the treatment of cancers through the administration of drugs that prevent or inhibit angiogenesis. For instance, thalidomide was used successfully by Dr. D'Amato and others to treat multiple myeloma in the 1990s. Subsequently, Dr. D'Amato began investigating other drugs with similar chemical structures to thalidomide, referred to as "analogs"—including lenalidomide and pomalidomide—for similar efficacy.

Defendants' invalidity contentions assert that the claimed methods of treatment would have been obvious in view of prior art showing that pomalidomide exhibited anti-angiogenesis activity—*i.e.*, similar activity to thalidomide or lenalidomide—when tested *in vitro* or *in vivo*, thereby suggesting efficacy against multiple myeloma. Ex. 26 (12/15/2017 Rule 3.3 Contentions (MOT Patents and '427 Patent)) at 102–08. Thus, limiting the requested set of data to only those documents containing [redacted]" necessarily—and improperly—excludes documents relevant to Defendants' invalidity claims in this case.

Furthermore, Defendants also assert lenalidomide and thalidomide as prior art compounds that render the asserted claims obvious. Knowledge of lenalidomide and thalidomide—their effects on the body, their doses, and their efficacy against multiple myeloma, for example—would have informed the person having ordinary skill in the art and led them to use pomalidomide to also treat multiple myeloma. *See, e.g.*, ECF No. 255 at 6. Due to the close chemical relationship between thalidomide, lenalidomide, and pomalidomide,[9] the prior art was already comparing the activity these three drugs exhibited in *in vitro* and *in vivo* testing and finding pomalidomide and lenalidomide to have similar but improved effects over thalidomide. Consequently, [redacted]"[10] is too narrow.

Celgene's objections to Defendants' requests are based on its disagreement with Defendants' invalidity contentions. This is improper. Defendants seek discovery of documents that are relevant to claims made in this case, and Celgene has provided no legitimate reason why

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Discovery Confidentiality Order entered in this case would be inadequate. For example, CASI continues to work with Defendants to locate the documents, licenses, and agreements identified in the subpoena, and the Discovery Confidentiality Order entered in this case contemplates the production, designation, and protection of nonparty confidential information. *See, e.g.*, ECF No. 152 (Discovery Confidentiality Order) at 3–6.

9 The patents-in-suit admit the close relationship between these drugs. The specifications of the MOT patents describe the invention as including "analogs and derivatives of thalidomide" and identify both lenalidomide and pomalidomide as the two most preferred compounds. *See, e.g.*, ECF No. 1, Ex. A ('262 patent) at 5:52–65; 9:17–50.

10 [redacted]

such discovery lacks proportionality. Defendants respectfully request an order compelling Celgene to produce the requested documents.

2. Celgene's Position

Defendants appear to be under the mistaken belief that the EntreMed litigations resulted in Celgene receiving the rights to voluminous patents and other intellectual property covering the use of pomalidomide for treating multiple myeloma. If it were true, then Celgene would have listed the EntreMed patents in the Orange Book for Pomalyst® and would have sued Defendants on them. This did not happen.

Defendants have failed to establish why the vast scope of EntreMed documents they seek—including the confidential agreements and documents concerning other products—are relevant and proportional to any issue in this case. Defendants contend that their request is relevant to (1) inventorship (citing 35 U.S.C. § 102(f)) and (2) obviousness (citing 35 U.S.C. § 103 and 35 U.S.C. § 102 (g)(2)), and they also argue that (3) "Celgene has provided no reason why [the EntreMed] discovery lacks proportionality." Defendants are incorrect on each point.

Inventorship: Defendants argue improper inventorship under 35 U.S.C. § 102(f) on the theory that Celgene allegedly stole the claimed inventions from EntreMed. But as Defendants know, Celgene filed the patent applications for the inventions claimed in the method-of-treatment patents-in-suit (invented by Dr. Zeldis) ***before*** it entered into any deal with EntreMed or received any data from EntreMed. Accordingly, Dr. D'Amato could not have been the inventor of Celgene's patents.

Nevertheless, Defendants point to D'Amato's '291 patent as allegedly covering pomalidomide. Defendants' argument, however, is based on Defendants' incorrect conclusion that the "3-aminothalidomide" compound in claim 1 of the '291 patent is pomalidomide. To be clear, the compound identified as "3-aminothalidomide" in the '291 patent is ***not*** pomalidomide. In fact, the structure of pomalidomide does not appear in the '291 patent at all. This is true despite the fact that the '291 patent discloses literally hundreds of millions (if not billions) of thalidomide analogs. Celgene explained this to Defendants in its Responses to Defendants' Invalidity Contentions concerning the '291 patent. *See* Ex. A at 200-01.

Defendants do not dispute the '291 patent's disclosure in this letter. In fact, they have finally conceded that Celgene is correct on this point in footnote 4 above. As such, Defendants attempt to bring ***new references*** (i.e., the '344 application and '391 application) into this case and make ***new arguments*** for why the vast scope of EntreMed documents they seek are supposedly relevant based on those new references. But the '344 application and '391 application: (1) are not in Defendants' invalidity contentions; (2) were not in Defendants' opening letter or reply letter in support of their application to compel; and (3) were not even in Defendants' original draft of this joint letter provided to Celgene on April 9, 2019. Instead, Defendants' new-found references and theories were not introduced until Defendants sent revisions to this letter to Celgene on April 17, 2019. Defendants' claim that these references were allegedly disclosed when Defendants cited to an entire docket from a different litigation—without ever mentioning the '344 or '391 application—lacks merit. Defendants' failure to timely disclose these references and theories undermines Defendants' claims of relevance.

Even assuming that Defendants' new references and theories are relevant—they are not—Defendants' eleventh-hour attempt to inject these new issues into this case, without even attempting to satisfy Local Patent Rule 3.7, supports rejecting Defendants' overly broad and

irrelevant fishing expedition. Indeed, Defendants admit that they are "continu[ing] to develop" new theories even today, ***2 years*** after this case was filed. As explained herein, however, these new theories are untimely, misguided, and unsupported.

As mentioned above, ***none*** of the D'Amato patents are listed in the Orange Book as covering pomalidomide or the use of pomalidomide for treating multiple myeloma. The D'Amato patents have never been asserted against Defendants, and they are irrelevant to this litigation. [redacted] Defendants wrongly assume that the license is relevant to Celgene's multiple myeloma method-of-treatment patents that are at issue in this case.

Moreover, as Celgene previously explained, Defendants do not have any inventorship claim in this case. Defendants admitted this at the in-person meet-and-confer—despite their claim to the contrary here—but argued that they can move to amend their pleadings.[11] Celgene submits that it is far too late in the case for such motion practice, especially given the futility of any such amendment.

Obviousness: Defendants argue invalidity under 35 U.S.C. § 102 (g)(2) on the theory that non-public work done by EntreMed allegedly renders obvious Celgene's claimed inventions. As an initial matter, Defendants do not explain how non-public, confidential materials could possibly be relevant to obviousness. As a matter of law, they are not. *See* 35 U.S.C. § 103(a); *see also, e.g.*, Ex. B, *Avanir Pharm., Inc. v. Actavis S. Atlantic LLC, et al.*, No. 11-704 (LPS) D.I. 462 at 64:11-65:7 (D. Del. Dec. 20, 2013) (affirming reasoning denying motion to compel because "the patient records are confidential," which means that "[t]hey are not prior art"). Indeed, even Defendants' Section 102(g) argument fails as they do not point to anything in their portion of the letter where pomalidomide was used for treating multiple myeloma, much less the specific methods claimed in the patents-in-suit. And despite the theory that Defendants advance, "§ 102(g) prior art must be somehow made available to the public in order to defeat another patent." *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1039 (Fed. Cir. 2001); *accord Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1306 (Fed. Cir. 2012) ("[O]ur case law establishes that . . . § 102(g) prior art must be somehow made available to the public in order to defeat another patent.").

As such, Defendants resort to arguing that "there is nothing to support Celgene's claim that the data and records sought were 'confidential' or concerned only 'confidential' subject matter when kept by EntreMed, before they were obtained by Celgene." But if this were true, then Defendants would have been able to obtain these materials publicly and would not be seeking them from Celgene. Furthermore, Defendants have served a subpoena on EntreMed's successor company, CASI Pharmaceuticals ("CASI"), [redacted] Defendants now claim that CASI is supposedly working with Defendants and that CASI supposedly has no issue producing documents under the DCO in this case. [redacted]

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[11] If Defendants truly had an inventorship claim in this case, then they should be able to easily point to their pleadings and include the relevant language in their portion of their letter. Their inability to do so is notable.

[12] Defendants have also subpoenaed Dr. D'Amato, [redacted]

[redacted], and Defendants have not provided any evidence to the contrary. In fact, Defendants have ignored multiple emails from Celgene requesting that Defendants provide responses received and communications with CASI regarding the subpoena. Defendants have also ignored Celgene's request to meet-and-confer regarding their refusal to provide this information. Even if Defendants' fishing expedition had merit, [redacted] This further counters Defendants' Section 102(g) argument.

Furthermore, Defendants' argument that "the burden of producing evidence of suppression or concealment is the patentee's (*i.e.*, Celgene's), and Celgene has made no such allegation to date" is wrong. As explained above, at the very least, [redacted] Defendants' inability to find publicly the information they seek—assuming any exists—would satisfy any alleged burden on Celgene to show that what Defendants seem to believe exists was suppressed or concealed. Moreover, "***a party asserting invalidity under § 102(g) [i.e., Defendants not Celgene]*** must prove facts by clear and convincing evidence establishing a prior invention that was not abandoned, suppressed, or concealed." *Apotex*, 254 F.3d at 1036 (emphasis added); *see also id.* at 1038 ("[T]he party asserting invalidity under § 102(g) must rebut any alleged suppression or concealment with clear and convincing evidence to the contrary."). Defendants cannot do so. Defendants' attempt to use Section 102(g) to justify discovery, therefore, lacks merit.

Disproportionality: As Defendants well know, the '291 patent and the patent applications that Defendants cite refer to hundreds of millions (if not billions) of thalidomide analogs. Such expansive discovery is, by definition, disproportionate to the needs of this case, which involves infringement of patents relating to a single compound (pomalidomide) for a single indication (multiple myeloma).

The disputed issues in this case are much different than the scope of D'Amato's patents; the disputed issues concern Celgene's patents to treating multiple myeloma with pomalidomide. Thus, in an attempt to fully resolve the dispute—not as a starting point for further negotiation—Celgene offered to produce, to the extent it exists and can be located after a reasonable search, [redacted][3] In the alternative proposal—if Defendants' request is not denied—[redacted] Defendants have not explained how anything else could be relevant and proportionate to the needs of this case. In fact, Defendants' portion of the joint letter is silent on how any settlements, licenses, or purchase agreements could allegedly relate to the disputed issues. [redacted]

In sum: Defendants' overly broad, disproportionate, and irrelevant request should be denied in its entirety. If granted, it will only lead to more motion practice, including presumably a

13 [redacted]

baseless motion to amend pleadings from Defendants [redacted]

C. Section C (Lenalidomide/Thalidomide Actions)

1. Defendants' Position

Defendants request a specific set of documents to be produced from other actions involving invalidity claims against Celgene's patents listed in the Orange Book as covering its Revlimid® (lenalidomide) and Thalomid® (thalidomide) products. *See* ECF No. 276 at 3–5. As explained above, both of these drugs are also used for the treatment of multiple myeloma, and thalidomide, lenalidomide, and pomalidomide are all closely-related chemical analogs. Additionally, thalidomide and lenalidomide are asserted as invalidating prior art compounds in Defendants' invalidity contentions.

Over the course of the Parties' meeting and conferring, Defendants have significantly narrowed the scope of these requests by reducing the categories of documents requested as well as the number of litigations concerned. *E.g.*, *compare* ECF No. 255 at 5–6 *with* ECF No. 276 at 3–5; ECF No. 315 at 3. Specifically, Defendants request the following documents from the identified actions: (a) invalidity/validity contentions; (b) transcripts for depositions of named inventors; (c) expert reports on invalidity/validity; (d) deposition transcripts for invalidity/validity experts; and (e) interrogatory responses and request for admission responses on invention/conception/reduction to practice/diligence and secondary considerations. *See* ECF No. 315 at 3. Defendants have limited the scope of the requested documents to those contentions, reports, and transcripts directly relevant to Defendants' invalidity and inventorship claims, and to Celgene's obviousness rebuttal (*e.g.*, secondary considerations) in this case. *See* ECF No. 255 at 6; ECF No 276 at 5. Thus, the requested documents are highly relevant to this case and should be promptly produced. *See* ECF No. 255 at 6–7 (citing cases compelling production of documents from other litigations); ECF No. 276 at 5–6 (same); *see also Zampetis*, 2018 WL 5729905, at *2.

Defendants only recently learned from Celgene that no experts were deposed in any of the identified litigations—thereby mooting Defendants' request for category (d) above—and that the only inventor deposed was Dr. Zeldis (although Celgene refused to disclose how many times he was deposed). During the Parties' March 29, 2019 in-court meet and confer, Celgene offered to produce a limited subset of Defendants' already-narrowed request:[14] (1) invalidity/validity contentions and expert reports on invalidity/validity redacted ***except for*** material related to inventorship and secondary considerations concerning multiple myeloma; (2) the unredacted transcripts for the depositions of Dr. Zeldis.

The Parties' remaining dispute as to these requests is whether the contentions and expert reports that Celgene offered to produce should have prior art invalidity arguments redacted, and whether it is overly burdensome for Celgene to produce written discovery (category (e) above) on inventorship and secondary considerations. In an effort to understand Celgene's burden

[14] In an effort to understand Celgene's alleged burdens and positions with respect to this dispute, counsel for the Mylan Defendants asked Celgene during the in-court meet and confer to consider modifying its prior proposal to include producing the Zeldis transcripts unredacted—and Celgene agreed. However, none of the defendants, including the Mylan Defendants, reached agreement with Celgene as to this category of documents at the in-court meet and confer.

objections, Defendants requested Celgene provide Defendants a list identifying the documents Celgene possesses from these litigations, whether the documents are marked confidential, and the identity of the parties who marked them confidential. Celgene refused.

Celgene's insistence on redacting the prior art invalidity arguments (including obviousness) from the contentions and expert reports to be produced is, again, based on Celgene's misguided view of relevance. Lenalidomide and thalidomide are structural analogs of pomalidomide, and their prior uses to inhibit angiogenesis or treat cancer generally, and multiple myeloma specifically, are relied upon by Defendants as invalidating prior art. Thus, invalidity theories advanced against patents claiming the use of those drugs to inhibit angiogenesis, treat cancer generally, or multiple myeloma specifically—which may include arguments and evidence establishing that all thalidomide analogs, including pomalidomide, would be reasonably expected to treat cancer generally or multiple myeloma specifically—whether found in written discovery responses, contentions, expert reports, or deposition transcripts, are directly relevant in this case. Furthermore, certain of the patents at issue in these other actions name the same inventor—Dr. Zeldis—and have the same specification as the MOT patents asserted in this case. *See* ECF No. 276 at 4–5.

Celgene has also put these drugs at issue through its own contentions by asserting secondary considerations of non-obviousness. ECF No. 255, Ex. 2 (Celgene's Rule 3.4A Contentions) at 185, 191, 323, 386–87. For example, Celgene claims that there was a long felt need for multiple myeloma treatment, a failure of others to develop safe and effective multiple myeloma treatments, and that pomalidomide was unexpectedly safe and effective. As a result, Celgene's statements in contentions, written discovery, and expert reports with respect to whether the patents at issue in the lenalidomide/thalidomide litigations were, for example, safe and effective treatments for multiple myeloma, are relevant to issues Celgene has raised in this case.

The obviousness sections that Celgene proposes to redact likely contain information relevant to these issues. For instance, Celgene's responsive contentions in this case mention secondary considerations (e.g., "long felt need") outside of the section in their response titled "secondary considerations." *Compare* ECF No. 255, Ex. 2 (Celgene's Rule 3.4A Contentions) at 185, 191, 323 *with id.* at 386–87. Similarly, Celgene's statements concerning whether there was a reasonable expectation of success, which are made in the obviousness section, are also relevant to claims of unexpected results. Celgene argues that the obviousness sections cannot be useful to Defendants because Defendants' contentions have already been served and no good cause exists for amending. Whether Celgene believes there to be good cause is not a proper basis for refusing discovery. Regardless, the obviousness arguments Celgene proposes to redact rely on some of the same prior art that is ***already*** contained in Defendants' contentions served in this case.[15] Celgene's prior statements responding to and discussing these prior art references are highly pertinent to this case.

Defendants previously understood Celgene's objections to the production of material from these litigations on the basis of third party confidentiality to be moot because Celgene acknowledged during the Parties' March 29, 2019 in-court meet and confer that these issues could be worked out. Celgene's position below retracts this acknowledgement and makes

[15] The invalidity contentions for one of the identified lenalidomide/thalidomide actions was filed publicly on the docket for that case and includes prior art also listed in Defendants' invalidity contentions in this litigation. *See Celgene Corp. v. Natco Pharma Limited et al.*, No. 2-10-cv-05197-SDW-LDW, ECF No. 422-2.

unsubstantiated statements regarding possible motion practice from third parties. Celgene's speculative assertions are without merit. It is customary practice in the Third Circuit to compel production of third-party confidential information. *See* ECF No. 255 at 4 n.4. Moreover, the Discovery Confidentiality Order entered in this case is sufficient protection for any nonparty confidential information produced in this case and Celgene has not proffered any reasons to the contrary. *See* ECF No. 152.

Thus, Defendants respectfully request an order compelling Celgene to produce the requested documents: (1) the prior art invalidity, secondary considerations, and inventorship sections of contentions and expert reports on invalidity/validity; (2) the unredacted transcripts for the depositions of Dr. Zeldis; and (3) responses to interrogatories and requests for admission concerning secondary considerations and inventorship.

2. Celgene's Position

As an initial matter, Defendants again improperly seek to convert Celgene's compromise offer into the new baseline, and then seek additional materials from there. Specifically, Defendants claim that "[t]he Parties' dispute as to these requests has [] been reduced to a disagreement over whether the contentions and expert reports that Celgene offered to produce should have prior art invalidity arguments redacted, and whether it is overly burdensome for Celgene to produce written discovery (category (e) above) on inventorship and secondary considerations." This is a transparent attempt by Defendants to take advantage of Celgene's efforts to resolve this dispute. Celgene's proposed compromise position was not a starting point for further negotiation; it was an offer to resolve the full scope of the request, which again seeks irrelevant, overly broad, unduly burdensome, and disproportionate discovery.

Celgene has already explained why materials concerning patents and products other than the patents and product at issue in this litigation are irrelevant. *See* D.I. 268 at 3-5. Celgene was, nonetheless, willing to work with Defendants to avoid burdening the Court. As such, during the in-court meet-and-confer, ***Mylan proposed***, and ***Celgene agreed***, that the parties resolve the dispute by Celgene agreeing to produce (1) invalidity/validity contentions and expert reports on invalidity/validity redacted except for material related to inventorship and secondary considerations concerning multiple myeloma; and (2) the unredacted transcripts for the depositions of Dr. Zeldis. These materials (while already overly broad and related to compounds ***other than*** the compound at issue in this case) would address Defendants' arguments regarding inventorship and secondary considerations. But certain other Defendants balked. They demanded the full scope of their request, even though they have not explained, and still cannot explain, the alleged relevance and proportionality.

Instead, Defendants argue that, because they assert alleged prior art purportedly concerning thalidomide and lenalidomide, then invalidity theories advanced ***by other lawyers, in other litigations***, ***concerning other products not at issue in this litigation*** are supposedly relevant and proportionate in this case. This begs serious questions: If the other lawyers could come up with certain invalidity theories, then why couldn't the six Defendants' do so on their own? Also, how do Defendants now expect to use invalidity theories from other cases and involving different drug products in the present case? While Defendants claimed at the meet-and-confer that they may move to amend their invalidity contentions, Celgene submits that there cannot possibly be any good cause, especially at this late stage of the case. Furthermore, the prejudice to Celgene—after this litigation has been ongoing for nearly two years—would be large, and the current schedule would have to be significantly delayed.

In any event, the majority of Defendants' arguments focus on secondary considerations. Defendants continue to ignore that Celgene offered to produce that information. Defendants' alleged justification for the remainder of the documents is limited to contentions. Defendants argue they are supposedly entitled to the contentions because "Celgene's prior statements responding to and discussing [certain] prior art references are highly pertinent to this case." Notably, Defendants provide no explanation for their position. Celgene has fully responded to Defendants' contentions in this case. To the extent that Defendants believed otherwise, they could have requested that Celgene clarify its positions. Defendants have not done so, and Celgene submits that it is far too late in this case for such a request in any event.

In sum, Defendants cannot establish relevance or proportionality for production of these materials. Defendants' request would force Celgene to review thousands of discovery requests and many thousands of pages of contentions and expert reports for third-party confidential information (and the specific discovery requests that Defendants ask for in this letter). This task would be unduly burdensome, extremely time consuming, and distract from advancing this case towards trial.[16] Defendants' overly broad, disproportionate, and irrelevant request should be denied. If granted, it will only lead to more motion practice, including, presumably, a baseless motion to amend contentions from Defendants and possibly motions for protective orders from numerous third parties.

D. Section D (Lenalidomide/Thalidomide Development)

1. Defendants' Position

These requests include two categories of documents concerning Celgene's development work on lenalidomide and thalidomide and their use in treatment for multiple myeloma. ECF No. 255 at 7. During the course of the Parties' meeting and conferring, Defendants proposed that Celgene agree to prepare a witness on these issues instead of producing the requested documents.[17] ECF No. 314 at 3. Celgene agreed with respect to one of these two categories [redacted] ut refused with respect to the remaining category (*i.e.*, Celgene's development of the dosage amount, dosing regimen, combination therapy with dexamethasone, and use as treatment for multiple myeloma for Revlimid®), arguing the topic was irrelevant because it did not concern pomalidomide and was too broad to prepare a witness. Celgene offered no suggestions as to what it would consider a reasonable scope.

During the Parties' March 29, 2019 in-court meet and confer and, in the interest of addressing Celgene's burden objection, Defendants asked Celgene whether it would consider the Parties' dispute resolved as to the first category and then consider with respect to the second category producing the following narrowed set of documents: Documents before May 15, 2003 showing the development of the dosage amount, dosing regimen, combination therapy with dexamethasone, and use as treatment for multiple myeloma for Revlimid®.[18] Defendants'

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[16] Celgene disagrees that it ever stated that third-party confidentiality was not a concern or that the "issues could be worked out."

[17] By this proposal, Defendants do not waive and expressly reserve all rights to the discovery of documents used to refresh the recollection of the witness.

[18] Celgene's claim that Defendants' now seek "even more discovery" than previously is incorrect. Defendants' Application to Compel additionally requests documents on "Thalomid®, and/or

proposal was based on the reasoning that Celgene's burden would be greatly reduced because Celgene—represented by the same counsel as in this case—has already collected, reviewed, and redacted a similar (or larger) set of documents as part of the lenalidomide/thalidomide litigations discussed above. Celgene refused to propose any reasonable alternative search scope or middle ground compromise, arguing that even running a search on already collected, reviewed, and produced documents would be too burdensome.

Defendants maintain the relevance of the requested documents. Celgene incorrectly contends that the requested documents cannot be relevant because they are "internal" documents. But Celgene's documents may contain admissions about the prior art, the performance of lenalidomide or thalidomide, the criticality (or lack thereof) of dosing or treatment regimen, the obviousness of combination therapy, the relationship between certain *in vitro/in vivo* testing and treatment for multiple myeloma, or other statements contradicting Celgene's contentions in this case, which are relevant to Defendants' invalidity theories based on those drugs.[19] Furthermore, claims of unexpected results relevant to the obviousness inquiry can be rebutted through indirect comparisons to the prior art. *See In re Fouche*, 439 F.2d 1237, 1241 (C.C.P.A. 1971) (use of indirect comparison between prior art and non-prior art compounds for unexpected results); *Ex Parte Humber*, 217 U.S.P.Q. (B.N.A.) 265 (Bd. Pat. App. & Inf. 1981) (showing of improved results through comparison with non-prior art). Additionally, documents dated after a patent's filing date can be used to support (or refute) unexpected results. *Cf. Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc*., 665 F.3d 1291, 1307–08 (Fed. Cir. 2011); *Knoll Pharm. v. Teva*, 367 F.3d 1381 (Fed. Cir. 2004). *See also* ECF No. 276 at 6–7.

If, as Celgene now contends below, Celgene's prior agreements were "sufficient to cover the information sought by this request," Celgene would not be continuing to object to Defendants' requests. Celgene's continued refusal to provide the witness and documents Defendants request is an admission that the scope of what Defendants seek is not coextensive with the discovery Celgene already agreed to provide, and demonstrates that Defendants' requests are not moot.

The requested documents are highly relevant to this case, and Celgene's speculation as to possible delays and motion practice fails to show that this discovery lacks proportionality. *See* Fed. R. Civ. P. 26(b)(1); *see also Zampetis*, 2018 WL 5729905, at *2. In addition to producing

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any lenalidomide or thalidomide product" (ECF No. 255 at 7), and, as Celgene's counsel admitted during the in-court meet and confer, Defendants' previous request for a witness on this issue was broader, in that it was not limited in time to before May 15, 2003. *See* ECF No. 315 at 3.

[19] Below, Celgene misrepresents comments made by counsel for Apotex during the meet and confer process regarding the scope of discovery under Rule 26. Specifically, Celgene selectively quotes Apotex's counsel as commenting that "all discovery is a fishing expedition," while neglecting to mention Apotex's counsel's repeated qualification that such fishing expeditions take place within "a defined pond," as recognized by this Court and others. *See, e.g., Edelson V, L.P. v. Encore Networks, Inc.*, No. 11-cv-5802 (KM-JAD), 2012 WL 4889439, at *6 (D.N.J. Aug. 13, 2012) (recognizing that a discovery request is not *per se* impermissible because it constitutes a "fishing expedition."); *Myers v. Prudential Ins. Co. of Am.*, 581 F. Supp. 2d 904, 913 (E.D. Tenn. 2008) ("Much of discovery is a fishing expedition of sorts, but the Federal Rules of Civil Procedure allow the Courts to determine the pond, the type of lure, and how long the parties can leave their lines in the water.").

the requested documents, Defendants respectfully request an order compelling Celgene to produce a witness as previously agreed with respect to the other category.

2. Celgene's Position

Defendants' request for "Lenalidomide/Thalidomide Development" documents now asks for ***even more discovery*** than Defendants' original application to compel. Specifically, Defendants now request a witness to testify concerning [redacted]. In other words, Defendants have turned their application to compel the production of documents into an application to compel Rule 30(b)(6) testimony as well. But Celgene's offer to produce a witness was a proposed compromise to resolve the entire dispute. Defendants again attempt to take advantage of Celgene's efforts to resolve this dispute and to use Celgene's compromise offer as a starting point for obtaining more irrelevant discovery. In any event, and as explained below, based on Defendants' representations in their April 17, 2019 version of this letter—where Defendants appeared to agree to take this issue out of dispute if Celgene agreed that the discovery it was offering as a compromise was sufficient to moot the request—Celgene confirms that the dispute for this category of discovery is moot.

Defendants' request for development documents of other compounds is nothing more than another fishing expedition. Defendants broadly demand "Documents before May 15, 2003 showing the development of the dosage amount, dosing regimen, combination therapy with dexamethasone, and use as treatment for multiple myeloma for Revlimid®." But Revlimid® is not at issue in this case, and Defendants have offered no legitimate reason for why these confidential, internal materials regarding a different compound are relevant here. Instead, Defendants' only relevance argument is that:

> Celgene's documents [concerning products not at issue in this litigation] ***may contain admissions*** … which are relevant to Defendants' invalidity theories.

Fishing for admissions is not a basis to allow discovery, let alone where the alleged "admissions" would concern a product other than pomalidomide. Nevertheless, counsel for Apotex has commented that "all discovery is a fishing expedition" during numerous meet and confers. Such an approach to discovery is directly counter to the Federal Rules.

Moreover, Defendants have not rebutted Celgene's showing of undue burden. Defendants argue that Celgene "has already collected, reviewed, and redacted a similar (or larger) set of documents as part of the lenalidomide/thalidomide litigations…." Defendants' suggestion, however, is an incorrect oversimplification of productions from prior cases dating back many years and, in any event, does not support the production of otherwise irrelevant materials. There is also no reasonable way to conduct a search of Celgene's materials for the broad, non-specific scope of materials that Defendants seek. Thus, Defendants' assumptions regarding undue burden are misplaced.

Defendants also incorrectly argue that Celgene did not explain what a reasonable scope of discovery would be for purposes of compromise. Specifically, Defendants ignore that Celgene has already agreed to produce a witness to discuss certain protocols and trials concerning lenalidomide in an effort to avoid burdening the Court with disputes in this case. *See* Ex. C at 2 (2/28/19 Ltr. from F. Calvosa to K. Reichenbach). During the meet-and-confer process, Celgene

also agreed to produce documents concerning the secondary considerations it has asserted in this case (including unexpected results), whether those materials support or refute Celgene's arguments. Defendants have not explained why Celgene's existing compromises are not sufficient to cover the information sought by this request as well. Defendants complained in their April 17th version of this letter that, because Celgene did not specifically state that this request is moot, then they must press forward with their request. Specifically, Defendants argued:

> If, as Celgene now contends below, Celgene's prior agreement to "produce a witness to discuss certain protocols and trials concerning lenalidomide" and "to produce documents concerning secondary considerations . . ." were "sufficient to cover the information sought by this request," Celgene would not be continuing to object. . . . Celgene does not argue Defendants' requests are moot.

So that this dispute may be mooted, Celgene agrees that the scope of discovery it has already agreed to produce is information sufficient to respond to Defendants' request. Thus, Celgene confirms that this request is now moot.

To the extent that Defendants disagree and demand each and every document that Celgene might possess on this subject matter, Defendants cannot establish relevance or proportionality for the discovery they seek. Moreover, compliance with Defendants' request would be unduly burdensome and significantly delay this case. Defendants' overly broad, disproportionate, and irrelevant request should be denied. If granted, it will only lead to more motion practice, including, presumably, a baseless motion to amend contentions from Defendants.

E. Section H (Pediatric Exclusivity)

1. Defendants' Position

a. Teva's, Aurobindo's, Hetero's, the Mylan Defendants', and Breckenridge's Position

During the Parties' March 29, 2019 in-court meet and confer, [redacted]. Consequently, Teva, Aurobindo, Hetero, the Mylan Defendants, and Breckenridge do not seek any documents pursuant to these requests at this time but otherwise reserve all rights to this discovery as appropriate.

b. Apotex's Position

Apotex seeks production of all documents in Celgene's possession concerning any pediatric exclusivity for pomalidomide, including any written requests from FDA for pediatric studies, and any documents, studies, or data, generated by Celgene in response to same.

Pediatric exclusivity is a non-patent marketing exclusivity granted by FDA to an NDA-holder who has performed studies of its drug in the pediatric population "that 'fairly respond' to a 'written request' from [FDA]." 21 U.S.C. § 355a(b)-(c); *Amgen Inc. v. Hargan*, 285 F. Supp. 3d 351, 357 (D.D.C. 2018). If FDA finds the studies acceptable, FDA will not approve any ANDAs for competing versions of the NDA holder's drug for six months beyond expiration of the NDA-holder's Orange Book patents and non-patent marketing exclusivities for the approved drug. *Id.*; *see also Amgen*, 285 F. Supp. 3d at 359; *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1341 (Fed. Cir. 2015). The FDA has issued a written request to Celgene to carry out pediatric studies for pomalidomide. Ex. 34 (FDA Written Requests Issued).[20] Importantly, pediatric exclusivity "***is not*** an extension of the term of a patent"; it only "extends the period during which FDA is barred from approving ANDAs filed by competing drug manufactures for six months beyond the patent's expiration date." *AstraZeneca*, 782 F.3d at 1341, 1343 (emphasis added)

In its Complaint for infringement, Celgene prays for relief from this Court "[a]n Order that the effective date of FDA approval of [Defendants' ANDAs] be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled." ECF No. 1, Compl., Prayers for Relief. 35 U.S.C. § 271(e)(4) prescribes the exclusive remedies available to Celgene should it prevail in its claims of infringement (beyond attorney fees). One of those remedies, § 271(e)(4)(A), allows this Court to "order the effective date of approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A).

Apotex respectfully submits that the "a date which is not earlier than the expiration of date of expiration of the patent"-language of § 271(e)(4)(A) permits this Court discretion as to whether to tie a patent owner's § 271(e)(4)(A) remedy to either the expiration of the patent, or to a later expiring marketing exclusivity period, such as pediatric exclusivity. *See AstraZeneca AB v. Impax Labs., Inc.*, 490 F. Supp. 2d 368, 377 (S.D.N.Y. 2007) ("[T]he clear and unambiguous language of the statute sets the date of the expiration of the patent only as the earliest effective date a court may order. . . . The Court agrees that the six-month period of pediatric exclusivity does not extend the term of the patents, but it does grant the patent holder a period of market exclusivity, which this Court has the power to enforce*"), aff'd, In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008). As an example, in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272 (D.C. Cir. 2004), during district court litigation successfully brought by the brand (ALZA) against a generic competitor, the district court's § 271(e)(4)(A) order stated "simply that 'the effective date of any

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[20] FDA may issue a written request for pediatric studies in approved indications that occur in all or part of the pediatric population (*e.g.*, the use of pomalidomide to treat multiple myeloma), or for unapproved indications (*e.g.*, the use of pomalidomide to treat brain cancer, an indication for which pomalidomide is currently not approved for). Ex. 35 (FDA, *Guidance for Industry: Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act* (September 1999)) at 6-7. Once granted, however, pediatric exclusivity attaches to all Orange Book patent and non-patent marketing exclusivities "for each drug product containing the studied active [ingredient] and for which the party submitting the studies holds the approved new drug application," and bars approval of all ANDAs for a period of six months following patent and non-patent marketing exclusivity expirations. *Id*. at 13; 21 U.S.C. § 355a(c). Thus, any written request from FDA, and any pediatric studies conducted by Celgene, for the use of pomalidomide in children for indications beyond multiple myeloma (such as brain cancer) are still relevant and discoverable because Celgene has pleaded that its remedy under § 271(e)(4)(A) should be tied to any pediatric exclusivity based on those non-multiple myeloma studies, instead of the expiration of its patents.

approval of Mylan's ANDA product shall be no earlier than the date of expiration of the '582 patent,'" despite the fact that the drug in question was already awarded pediatric exclusivity. *Mylan*, 389 F.3d at 1277. Similarly, in *Roche Pal Alto LLC v. Apotex, Inc.*, 526 F. Supp. 2d 985 (N.D. Cal. 2007), the court declined to enforce the brand's pediatric exclusivity, and instead tied the brand's § 271(e)(4)(A) remedy to expiration of the patent found infringed. *Roche*, 526 F. Supp. 2d at 1000; *see also, In re Omeprazole*, 536 F.3d at 1368-69.

Because, in the event Celgene succeeds in any of its infringement claims, this Court has discretion as to whether to tie Celgene's § 271(e)(4) remedy to either the expiration of a patent-in-suit found infringed and not invalid, or to the expiration of any pediatric exclusivity Celgene is granted, Apotex respectfully submits that the pediatric exclusivity documents Apotex seeks are squarely relevant to the 271(e)(4)(A) remedy Celgene is seeking in this case. If an inspection of those documents reveal that Celgene is not entitled to pediatric exclusivity because Celgene did not comply with the Pediatric Exclusivity statute or FDA regulations or rules—for instance, by carrying out studies that do not "fairly respond" to FDA's written request, *see Amgen*, 285 F. Supp. 3d at 359—Apotex should be permitted to argue during the remedy phase of this case that, should Celgene succeed in any of its infringement claims, Celgene's 271(e)(4)(A) remedy should not be tied to any grant of pediatric exclusivity, and should instead be tied simply to the expiration of the patent. Celgene raises no arguments against discoverability beyond relevance. ECF No. 268 at 8-9.

Celgene misrepresents Apotex's relevancy argument below by asserting that Apotex "submi[ts] that the Court has discretion over ***whether FDA can approve an ANDA within an additional six months after the current expiration date of Celgene's patents***"—Apotex makes no such submission. Apotex simply submits that, in the event Celgene were to succeed in its infringement claims, in fashioning its order to implement Celgene's § 271(e)(4)(A) remedy, this Court has discretion as to whether to tie that remedy—an order enjoining FDA from granting effective approval of Defendants' ANDAs until "a date which is not earlier than the date of expiration of the patent which has been infringed"—to either the expiration of Celgene's patents or to the expiration of any pediatric exclusivity Celgene is granted for pomalidomide. Celgene's only argument against this Court having discretion to fashion its own § 271(e)(4)(A) order is predicated on the text of the Pediatric Exclusivity statute—but that statute is directed to FDA, not the courts. 21 U.S.C. § 355a; *see also, Amgen*, 285 F. Supp. 3d at 364-65 (finding that the Pediatric Exclusivity statute is an "authorizing statue" that bestows statutory responsibilities on FDA); *Roche*, 526 F. Supp. 2d at 1000. By contrast, the Hatch-Waxman remedies statute—codified at § 271(e)(4), and which Apotex relies upon for its relevancy arguments—is expressly directed to the courts, and by its own plain language allows this Court certain discretion in fashioning its § 271(e)(4)(A) order.[21]

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[21] Celgene mischaracterizes the cases Apotex is relying on when it states that "each court in the cases Apotex cites explicitly relies on the [Pediatric Exclusivity] statute to enforce the pediatric exclusivity requirement." In fact, in both *Mylan* and *Roche*, the district courts did not enforce the pediatric exclusivity granted to the brand. *Mylan*, 389 F.3d at 1277; *Roche*, 526 F. Supp. 2d at 1000. And while in *AstraZeneca* the court did consider the Pediatric Exclusivity statute, and ultimately concluded that it had "the power to enforce" the brand's pediatric exclusivity, *AstraZeneca*, 490 F. Supp. 2d at 377, Apotex respectfully submits that the court's opinion makes clear that this power is discretionary, as the power to enforce necessarily includes the power to not enforce. Moreover, Celgene's reliance on *Mylan* is entirely misplaced. *Mylan* involved a suit against FDA by the generic (Mylan) seeking a determination that FDA's rescission of final approval for Mylan's ANDA was unlawful. *Mylan*, 389 F.3d at 1278. However, Celgene does not dispute that the district court order in the underlying patent

Finally, this Court should reject Celgene's request that any discovery on this topic be bifurcated and delayed until the remedies phase of the case. Celgene itself is currently seeking discovery from Defendants on its exceptional case claim for attorney fees pursuant to 35 U.S.C. § 285, which is a remedial statute. Ex. 36 (March 27, 2019 Ltr. from F. Calvosa to B. Murray) at 9. There is no principled reason why Celgene should be permitted to request and secure discovery on its exceptional case claim for attorney fees now, but Apotex should have to wait until the remedies phase of the case to secure discovery on the § 271(e)(4)(A) remedy Celgene has pleaded and is seeking from this Court. Moreover, as Celgene does not argue against production on the ground that such production would be burdensome, the documents should be produced during the fact discovery period that all parties have agreed to.

Apotex thus respectfully requests that the Court order Celgene to produce the requested pediatric exclusivity documents.

2. Celgene's Position

During the parties' in-court meet-and-confer, Defendants ***agreed*** that any pediatric studies are ***irrelevant*** to the merits phase of the case. Instead, Defendants argue that the studies are supposedly relevant to determining the length of the permanent injunction after Celgene wins on the merits.

While Celgene disagrees that the pediatric studies are relevant to the length of injunctive relief, Celgene, in an effort to compromise, offered to produce any pediatric studies concerning pomalidomide for multiple myeloma if Celgene ever generates such materials. Every Defendant except Apotex recognizes that only pediatric studies concerning pomalidomide for multiple myeloma—the only drug and indication at issue in this case—are even arguably relevant to the merits of this case. As such, each Defendant except for Apotex has accepted Celgene's compromise position to produce materials concerning pediatric studies for multiple myeloma.

Apotex demands Celgene's pediatric studies regarding brain cancer—which is not an indication at issue in this case—based on Apotex's "submi[ssion]" that the Court has discretion over whether the ***FDA*** can approve an ANDA within an additional six months after the current expiration date of Celgene's patents. ***No court has ever held that such discretion exists***, and the *Omeprazole* and *Mylan* decisions that Apotex cites ***enforce*** the six-month exclusivity period.[22]

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infringement suit tied the brand's § 271(e)(4)(A) remedy to expiration of the patent infringed, and not the expiration of pediatric exclusivity that the brand had been granted, which supports Apotex's position here. *Id*. at 1277. Finally, Celgene's attempt to distinguish *Roche* on the ground that the patents there had expired is misplaced—in *Omeprazole* the patents there had also expired, yet the district court decided to enforce the pediatric exclusivity granted there. *In re Omeprazole*, 536 F.3d at 1368. Thus, patent expiration is irrelevant to the issue of whether this Court has discretion to tailor its § 271(e)(4)(A) order.

[22] The *Roche* decision Apotex cites is inapplicable to the facts at hand. There, the Court did not enforce the pediatric exclusivity period because the patent had already ***expired***. *See* 526 F. Supp. 2d at 1000. Here, Celgene's patents do not expire for another ten-plus years. Furthermore, Apotex's claim about the *Mylan* case is directly contradicted by the appellate court's decision in the matter. *See* 389 F.3d 1272 at 1282-84.

Furthermore, the statue for pediatric exclusivity unambiguously states that:

> (B) if the drug is the subject of a listed patent for which a certification has been submitted under [paragraph IV], and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under ... section 355(j)(5)(B) of this title ***shall be extended by a period of six months*** after the date the patent expires (including any patent extensions).

21 U.S.C. § 355a(c)(2)(B) (emphasis added). While Apotex argues that this statute is directed to the FDA, and not the Court, each court in the cases that Apotex cites explicitly relies on the above statute to enforce the pediatric exclusivity requirement. In short, Apotex's statutory interpretation argument is misplaced. The statute's language is clear that there is no discretion in granting the remedy concerning FDA approval of an ANDA provided for products with pediatric exclusivity under the Hatch-Waxman Act. Apotex's request should be denied.

Celgene respectfully submits that if the Court is inclined to grant Apotex's requested discovery, then that discovery be bifurcated until the "remedy phase of this case," given Apotex's sole relevance argument. Apotex argues that "Celgene itself is currently seeking discovery from Defendants on its exceptional case claim for attorney fees pursuant to 35 U.S.C. § 285, which is a remedial statute." As shown in the letter Apotex cites, Celgene's exceptional case argument is not the sole argument in support of the deposition testimony that Celgene seeks. *See* Ex. 36 at 9 ("The testimony sought by this Topic is relevant to both Celgene's infringement and exceptional-case claims."). The same is not true for Apotex. Apotex does not deny that its sole relevance argument is related to the "remedy phase of this case" and Apotex's discovery should, at best, be bifurcated for that phase of the case.

* * *

As always, we thank the Court for its attention to this matter and the parties request that the Court set a hearing to address these remaining disputes at the Court's earliest convenience.

Respectfully submitted,

/s/ Liza M. Walsh

Liza M. Walsh

Enclosures
cc: All Counsel of Record (*via ECF & email*)

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., and TEVA PHARMACEUTICALS USA, INC.,** **Defendants.**	**Civil Action No. 17-3159 (ES)(MAH)** **Hon. Esther Salas, U.S.D.J.** **Hon. Michael A. Hammer, U.S.M.J.** **HIGHLY CONFIDENTIAL**
CELGENE CORPORATION, **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., and BRECKENRIDGE PHARMACEUTICAL, INC.,** **Defendants.**	**Civil Action No. 17-3387 (ES)(MAH)** **Hon. Esther Salas, U.S.D.J.** **Hon. Michael A. Hammer, U.S.M.J.** **HIGHLY CONFIDENTIAL**

PLAINTIFF'S RESPONSES TO DEFENDANTS' INVALIDITY CONTENTIONS WITH RESPECT TO U.S. PATENT NOS. 8,198,262; 8,673,939; 8,735,428; AND 8,828,427

5013 is lenalidomide, then this just adds to the numerous codenames that Defendants allege a POSA would have known all related to one compound at the time of the inventions claimed in the MoT Patents. Celgene contends that yet another codename would have further added to the confusion a POSA would have been faced with regarding the identity of any IMiD. Richardson IV is silent on every element of the claimed inventions.

Moreover, Defendants ignore that multiple abstracts on the same pages as Richardson IV evidence the laundry list of other compounds that would have been available to a POSA. Defendants do not comment on these other possible therapies due to hindsight.

Defendants do not provide any colorable reason why a POSA would have been motivated to combine the disclosures of Richardson IV with the disclosures of any other reference cited by Defendants. Defendants' reliance on Richardson IV is based on hindsight.

(yy) The '291 Patent

Defendants contend that "[t]he '291 patent discloses '[a] method of treating undesired angiogenesis in a human or animal comprising the step of administering to the human or animal with the undesired angiogenesis a composition comprising an effective amount of . . . 3-aminothalidomide," that "3-aminothalidomide is another name for pomalidomide," and that "undesired angiogenesis [] 'occurs in blood borne tumors' and 'leukemia.'" IC at 56-57 (citing '291 patent at 3:23-30 and claims 1, 65, 77). A POSA would not have been motivated to arrive at the claimed invention based on the '291 patent, let alone with any reasonable expectation of success.

The '291 patent does not use the term "pomalidomide" or link the term "3-aminothalidomide" to any particular structure. It also does not use any of the other codenames that Defendants contend refer to the compound that was later named pomalidomide. 3-aminothalidomide is not a proper chemical name and it does not use proper chemical

nomenclature. The '291 patent does, however, teach that 3-aminothalidomide is not the compound that was later named pomalidomide. For example, the '291 patent discloses thalidomide-based structures with substituents at different "R" positions. The compound that was later named pomalidomide would have had an amino group at the 4-position, not the 3-position. *See* '291 patent at cols. 5-7. The '291 patent is silent on 4-aminothalidomide. This adds to the confusion present in the alleged prior art as a whole.

The '291 patent also fails to disclose the compound that was later named pomalidomide at all, even among its billions of compounds. *See generally* '291 patent. Specifically, the '291 patent does not include a picture or drawing of the compound that was later named pomalidomide, and none of the "formulae" disclosed in the '291 patent can be used to create that compound. Indeed, even the closest "formula," "formula B," cannot be used to create the compound that was later named pomalidomide, at least because R8 cannot be a nitrogen atom without substituents, and neither R13 nor R16 can be NH (*see* '291 patent at 7:1-8:15), both of which are required for pomalidomide.

Further, the '291 patent does not disclose any in vivo testing, let alone in MM, with or without dexamethasone. The '291 patent also does not mention MM, despite mentioning a laundry list of angiogenesis-associated conditions. *See, e.g.*, '291 patent at cols. 1-3, 5, 14-15 and claims. The only "blood borne" tumor mentioned in the '291 patent is leukemia. *See, e.g.*, *id.* at 5:31-34.

As described herein, a POSA would not have reasonably expected any correlation between decreasing angiogenesis, especially in vitro, and clinical results in MM. Nor can Defendants credibly contend that all compounds known to have an anti-angiogenic effect in some assays would reasonably be expected to treat all conditions allegedly associated with

Dated: April 20, 2018

By: _____

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
Marta A. Godecki
Brian J. Forsatz
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Anthony M. Insogna
Steven J. Corr
Cary Miller, Ph.D.
Matthew J. Hertko
JONES DAY
4655 Executive Drive
Suite 1500
San Diego, CA 92121
(858) 314-1200

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Celgene Corporation

EXHIBIT C

quinn emanuel trial lawyers | new york
51 Madison Avenue, 22nd Floor, New York, New York 10010-1601 | TEL (212) 849-7000 FAX (212) 849-7100

WRITER'S DIRECT DIAL NO.
(212) 849-7569

WRITER'S EMAIL ADDRESS
frankcalvosa@quinnemanuel.com

February 28, 2019

HIGHLY CONFIDENTIAL
VIA E-MAIL

Kristen Reichenbach
Kirkland & Ellis LLP
555 California Street
San Francisco, California 94104
kristen.reichenbach@kirkland.com

Re: *Celgene Corp. v. Hetero Labs. Ltd. et al.*, Civil Action No. 17-3387 (D.N.J) (ES)(MAH)

Dear Kristen:

We write to follow up on the parties' February 22, 2019 meet and confer regarding Defendants' proposed compromises to resolve all issues set forth in their application to compel production of materials from Celgene. *See* D.I. 255, 268, 276, 297. In the interest of compromise, and to avoid burdening the Court with resolution of the issues Defendants have raised, Celgene would be willing to agree to the production of certain discovery enumerated below if Defendants agree that this fully resolves all issues raised in their application.

Cancellation Action Directed to Mexican Patent No. 292949

Defendants sought production of non-privileged documents relating to cancellation proceedings concerning Mexican Patent No. 292949. D.I. 255 at 12. Celgene opposed Defendants' application on the basis of, among other things, lack of relevance, privilege, and undue burden (especially with respect to the impossibility of separating privileged information from Celgene's records regarding the proceeding). D.I. 268 at 9. On Friday's call, Defendants represented for the first time that they would be willing to accept a copy of the filings in the cancellation proceeding that is obtained from the Mexican Patent Office. Celgene maintains that the Mexican proceeding is irrelevant to the issues in this case. In the interest of compromise and resolving all of Defendants' discovery disputes, however, Celgene would agree to obtain and produce to Defendants a copy of the filings in the Mexican Patent Office concerning the cancellation proceeding. Celgene's proposed agreement is based on Defendants withdrawing

their request for Celgene's internal documents regarding this subject matter and Defendants' agreement not to raise such a request again in the future.

Clinical Trial Protocols For Lenalidomide

Defendants sought clinical trial protocols, and certain related materials, regarding lenalidomide clinical studies referenced in two declarations submitted by Dr. Jerome B. Zeldis during prosecution of U.S. Patent No. 7,968,569 (the "'569 patent"). D.I. 255 at 9-10. As you know, the '569 patent is not in-suit in this action. It involves methods of treatment with lenalidomide, not pomalidomide (the active ingredient actually at issue in this proceeding). As such, Celgene opposed Defendants' application on the basis of, among other things, lack of relevance. D.I. 268 at 7. Defendants have now offered to drop this request if Celgene agrees to provide a 30(b)(6) witness prepared on Topic Nos. 58 and 59 of Defendants' 30(b)(6) notice. 2/22/19 e-mail from K. Reichenbach to F. Calvosa.

Topic No. 58 seeks testimony regarding "[t]he protocols and trials described in the Declaration By Jerome B. Zeldis signed October 26, 2005 submitted during the prosecution of the application that issued as U.S. Patent No. 7,968,569, including the protocols and trials described in paragraphs 5-6 and Exhibits D-K." Topic No. 59 seeks "[t]he protocols and trials described in the Declaration By Jerome B. Zeldis signed May 30, 2006 submitted during the prosecution of the application that issued as U.S. Patent No. 7,968,569, including the protocols and trials described in paragraphs 5-6 and Exhibits D-G."

Celgene maintains that information concerning different active ingredients and different patents than those at issue in this proceeding is irrelevant. Nevertheless, in the interest of compromise and resolving all of Defendants' discovery disputes, Celgene would agree to produce a witness to provide testimony regarding its current knowledge of the non-privileged facts (if any) concerning the protocols and trials described in the declarations identified in Topic Nos. 58 and 59 of Defendants' 30(b)(6) notice. Celgene's proposed agreement is based on Defendants withdrawing their request for the documents regarding this subject matter and Defendants' agreement not to raise such requests again in the future.

Documents Concerning the Development of Lenalidomide and Thalidomide

Defendants sought production of documents concerning Celgene's development work on lenalidomide and thalidomide and the use of those compounds in treatment for multiple myeloma. D.I. 255 at 7. Lenalidomide and thalidomide are not the active ingredient at issue in this proceeding and the request seeks almost every document in Celgene's possession over a twenty-plus year period. Further, Celgene's internal development work is irrelevant to the issues in this case. As such, Celgene opposed Defendants' application on the basis of, among other things, lack of relevance, overbreadth, undue burden, and disproportionality. D.I. 268 at 5-6. Defendants have now offered to drop their request for the documents sought if Celgene agrees to provide a 30(b)(6) witness prepared to testify concerning "Celgene's development of the dosage

amount, dosing regimen, combination therapy with dexamethasone, and use as treatment for multiple myeloma for Revlimid®, [redacted] 2/22/19 e-mail from K. Reichenbach to F. Calvosa.

Celgene maintains that its internal development work regarding a product not at issue in this case is irrelevant and that preparing a witness to testify on the scope of information that Defendants seek would be unduly burdensome (if not impossible), and disproportional to the needs of the case. But in the interest of compromise and resolving all of Defendants' discovery disputes, Celgene would agree to produce a witness to provide testimony regarding its current knowledge of the non-privileged facts (if any) regarding [redacted] Celgene's proposed agreement is based on Defendants withdrawing their request for the documents regarding this subject matter, Defendants withdrawing their request for the portions of the proposed deposition topic to which Celgene objects, and Defendants' agreement not to raise such requests again in the future.

Documents From Litigations Concerning Lenalidomide and Thalidomide

Defendants sought production of documents from other litigations involving Celgene's patents listed in the Orange Book as covering products not at issue in this case—i.e., Revlimid® (lenalidomide) and Thalomid® (thalidomide). D.I. 255 at 5-7. Given the number of litigations identified, the vast amount of documents involved in those litigations, third-party confidentiality, and that the Revlimid® (lenalidomide) and Thalomid® (thalidomide) products and patents are not at issue in this case (nor are the same issues involved in those litigations in dispute here), Celgene opposed Defendants' application on the basis of, among other things, lack of relevance, undue burden, overbreadth, and disproportionality. D.I. 268 at 3-5. In sum, Defendants' request amounted to nothing more than a fishing expedition.

On Friday's call, Defendants offered to "narrow" their request to seek all invalidity contentions, all responses to invalidity contentions, all expert reports, all expert deposition transcripts, all named inventor deposition transcripts, and all discovery requests (interrogatories, requests for production, and requests for admission) and responses to those requests to the extent that they relate to inventorship of the inventions concerning Revlimid® and Thalomid®, conception and reduction to practice of the inventions concerning Revlimid® and Thalomid®, and secondary considerations of non-obviousness asserted in the other litigations. Defendants' proposed "narrowed" request remains unreasonably broad, irrelevant, disproportionate to the needs of the case, and impinging on third-party confidentiality. Celgene would be unduly burdened in complying with such a request. Celgene believes, however, that there is a middle ground for compromise.

In Defendants' reply letter in support of their application to compel, Defendants argued that the information they seek is relevant to issues of inventorship and secondary considerations

directed to the treatment of multiple myeloma in this case. D.I. 276 at 3-6. Celgene maintains that Defendants have failed to explain the alleged relevance. Nonetheless, in the interest of compromise and resolving all of Defendants' discovery disputes, Celgene would be willing to produce invalidity contentions, responses to invalidity contentions, and expert reports from the eleven litigations identified by Defendants in D.I. 276 at pages 4 to 5 to extent that those materials exist, are in Celgene's possession, custody, or control, and are related to:
(1) inventorship of the inventions claimed in the patents-in-suit in those proceedings; and/or
(2) secondary considerations regarding the treatment of multiple myeloma (i.e., long-felt need and unexpected results) that Celgene raised in those proceedings. Celgene's proposed offer is based on Defendants withdrawing their request for the other documents Defendants have sought from the other litigations and Defendants' agreement not to raise such requests again in the future.

* * *

Celgene's above offers are made based on the understanding that this resolves all issues that Defendants raised in their application to compel. Please let us know if Defendants agree to Celgene's attempt to resolve Defendants' application. We are available to meet and confer on these issues tomorrow morning or anytime Monday, if necessary.

Best regards,

Frank C. Calvosa

EXHIBIT 36

quinn emanuel trial lawyers | new york
51 Madison Avenue, 22nd Floor, New York, New York 10010-1601 | TEL (212) 849-7000 FAX (212) 849-7100

WRITER'S DIRECT DIAL NO.
(212) 849-7569

WRITER'S EMAIL ADDRESS
frankcalvosa@quinnemanuel.com

March 27, 2019

HIGHLY CONFIDENTIAL
VIA E-MAIL

Brian P. Murray
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
bmurray@taftlaw.com

Re: *Celgene Corp. v. Hetero Labs Ltd., et al.*, Civil Action No. 17-3387 (D.N.J.) (ES)(MAH)

Dear Brian:

We write regarding Apotex's Objections and Responses to Celgene's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6) ("Apotex's Objections"), dated March 5, 2019. As described further below, Apotex's Objections are improper.

Apotex's General Objections and Objections Common To Many Topics

"beyond Apotex Inc.'s ANDA product"

Apotex objects to each of Topic Nos. 5, 6, 10, and 14 as seeking information "beyond Apotex Inc.'s ANDA product," because such information is purportedly "irrelevant to the claims and defenses in this case." These objections are improper. Celgene has defined Apotex's "ANDA Products" to mean "any pomalidomide-containing pharmaceutical products currently or formerly described in ANDA No. 210164." This definition covers only products that are or ***were*** the subject of Apotex's ANDA. That Apotex may have made changes to its products over time does not mean that discovery is not proper for any product(s) that was/were formerly the subject of Apotex's ANDA.

Moreover, following a meet-and-confer and the exchange of several letters, Apotex agreed, in the context of its document production, that it "will produce all non-privileged information in [its] possession, custody, or control concerning the research and development of [its] ANDA Products." *See* 11.16.18 Ltr. from Murray at 2. Apotex cannot withhold on

Topic. For the reasons discussed above, those objections are improper and Apotex should withdraw them and/or confirm that it is not withholding testimony based on those objections.

Apotex refuses to produce a witness on this Topic. That is improper. To the extent that Apotex has established relationships with third parties [redacted] pertaining to the sale, distribution, promotion, or marketing of its ANDA Products, such information is relevant to the potential induced and/or contributory infringement by those third parties. Indeed, Apotex agreed to produce documents concerning such relationships in response to Celgene's motion to compel. Accordingly, please supplement this response to provide a witness to testify to the full scope of this Topic without limitation, or inform us of your availability to meet and confer.

Topic No. 18

This Topic seeks information regarding when Apotex first became aware of the patents-in-suit. Apotex has propounded many of the objections discussed above in response to this Topic. For the reasons discussed above, those objections are improper and Apotex should withdraw them and/or confirm that it is not withholding testimony based on those objections.

Apotex refuses to produce a witness on this Topic. That is improper. The testimony sought by this Topic is relevant to both Celgene's infringement and exceptional-case claims. Accordingly, please supplement this response to provide a witness to testify to the full scope of this Topic without limitation, or inform us of your availability to meet and confer.

Best regards,

Frank C. Calvosa